METRIC

A-A-20172B
May 14, 2002
SUPERSEDING
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COMMERCIAL ITEM DESCRIPTION

FORMULA, INFANT

The U.S. Department of Agriculture (USDA) has authorized the use of this Commercial Item Description.

1. SCOPE. This Commercial Item Description (CID) covers infant formula packed in commercially acceptable containers, suitable for use by Federal, State, local governments, and other interested parties.

2. PURCHASER NOTES.

2.1 PURCHASERS *shall specify* the following:

- Type(s), style(s), class(es), and container and packaging size(s) of infant formula products required (Sec. 3).

2.2 PURCHASERS *may specify* the following:

- Packaging requirements other than commercial (Sec. 10).

3. CLASSIFICATION. The infant formula products shall conform to the following list which shall be specified in the solicitation, contract, or purchase order.

Type(s), style(s), class(es), and container and packaging size(s)

Type I - Infant formula iron-fortified
(Iron shall supply not less than 1.48 mg of iron (Fe) per 100 Kilocalories [10.0 mg iron (Fe) per liter] at standard dilution. The source of iron shall comply with Direct Food Substances Affirmed as Generally Recognized as Safe (21 CFR Part 184).

Type II - Infant formula with low-iron
(Less than 1 mg of iron (Fe) per 100 Kilocalories [6.7 mg iron (Fe) per liter) at standard dilution. Low iron infant formula is deficient. Supplemental iron is required if fed to infants as the sole source of food.)

Style A - Milk-based/Whey-based (for infants not allergic to milk)
Style B - Soy-based (for infants allergic to milk but not to soy)
Style C - Hypoallergenic (for infants allergic to milk and soy-based infant formulas)

Class 1 - Powder
Class 2 - Liquid, concentrate
Class 3 - Ready-to-use

Container and packaging sizes

a. Powder
(1) 30.05 g (1.06 oz) per packet, 16 packets per carton, 6 cartons per case
(2) 30.05 g (1.06 oz) per pouch, 48 pouches per case
(3) 340.19 g (12 oz) per can, 6 cans per case
(4) 396.89 g (14 oz) per can, 6 cans per case
(5) 453.59 g (16 oz) per can, 6 cans per case
(6) 907.18 g (32 oz) per can, 6 cans per case
(7) 1.134 kg (40 oz) per can, 4 cans per case
(8) Other

b. Liquid, concentrate
(1) 384.46 mL (13 fl oz) per can, 24 cans per case
(2) 384.46 mL (13 fl oz) per can, 12 cans per case
(3) 384.46 mL (13 fl oz) per can, 6 cans per case
(4) Other

c. Ready-to-use
(1) 236.59 mL (8 fl oz) per can, 24 cans per case
(2) 236.59 mL (8 fl oz) per can, 12 cans per case
(3) 946.35 mL (32 fl oz) per can, 6 cans per case
(4) Other

4. MANUFACTURER'S/DISTRIBUTOR'S NOTES. Manufacturer's/distributor's products *shall meet* the requirements of the:

- Salient characteristics (Sec. 5).
- Manufacturer's/distributor's product assurance (Sec. 7).
- Regulatory requirements (Sec. 8).
- Quality assurance provisions (Sec. 9).
- Packaging requirements other than commercial: *as specified by the purchaser* (Sec. 10).

5. SALIENT CHARACTERISTICS.

5.1 Processing. The infant formula products shall be formulated and packaged in accordance with current good manufacturing practices (21 CFR Part 110). The liquid formulas shall also comply with Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers (21 CFR Part 113). The infant formulas shall comply with Food and Drug Administration (FDA) Infant Formula Act of 1980 and the 1986 Amendments, the Infant Formula Program - Import and Domestic, Chapter 21 - Food Composition, Standards, Labeling and Economics, and with the following applicable CFR's:

Foods for Special Dietary Use	21 CFR Part 105.65, Subpart B
Infant Formula Quality Control Procedures	21 CFR Part 106
Infant Formula	21 CFR Part 107

5.2 Finished product.

5.2.1 Appearance and color. The infant formula shall be of medium viscosity, be free flowing, and have a uniform consistency and appearance. All infant formulas shall possess a white to light cream color and shall be uniformly colored throughout, characterize the type, and class it represents.

5.2.2 Body and texture. The infant formula shall be free from gelation, which includes such factors as surface ripple, unevenness of flow, and lumpiness. The infant formula shall be free from creaming (the separation of fat), protein agglomeration (the cohesion of microscopic protein particles of sufficient size to be visible), and extraneous material. Milk-based/whey-based infant formula shall be free from coarse milk and whey-based solids precipitate or sedimentation. The powder formula shall be smooth, uniform, free from lumps, or graininess.

5.2.3 Odor and taste. At standard dilution, as applicable, **ALL CLASSES** of infant formulas shall have the normal characteristic odor and taste, free from rancidity and other undesirable odors and tastes.

5.2.4 Age requirement and shelf life. The age requirement of the infant formula at the time of shipment shall comply with FDA's regulations and requirements after packaging. Cans and can coatings shall meet FDA's requirements for safe contact with packaged infant formula. All classes of infant formulas shall have a minimum of one-year shelf life from the packaged date. Each infant formula container shall declare a "use by" date. The "use by" date is to inform purchasers and users that the infant formula, until that declared date, will contain the quantity of each nutrient as specified on the label and that the formula is otherwise of an acceptable quality. The infant formula product should be discarded when the calendar current date is after the **"**use by" date.

5.3 Foreign material. Infant formula products shall be clean, sound, wholesome, and be free from foreign material such as, but not limited to, dirt, insect parts, hair, wood, glass, or metal.

5.4 Dilution. At standard dilution, all classes of infant formulas shall supply 20 Kcal per fluid ounce.

5.4.1 Powder (Class 1). Powder infant formula shall be of suitable particle size and solubility such that it will readily disperse in warm water. Manufacturer's instructions are required for the amount of powder infant formula and water to make up a standard dilution. When prepared in accordance with label instructions, the infant formula shall supply the labeled nutritional requirements. When tested, a 25 g sample shall contain not more than 15.0 mg scorched particles when compared to the American Dairy Products Institute Scorched Particle Standards for Dry Milks.

The microbiological determinations of powder infant formula shall be in accordance with the following referenced methods. The FDA may require additional tests, as newly emerging food safety information is made available.

Methods in the Official Methods of Analysis of the AOAC or the FDA, Bacteriological Analytical Manual (BAM) specified for infant formula currently in effect on the date of solicitation shall be used. Upon microbiological analysis, the test results of powder infant formula shall meet the following values:

Salmonella - Negative
Listeria monocytogenes - Negative
Coliforms - Not more than 10 per gram
Fecal coliforms - Not more than 3 per gram
Escherichia coli - Not more than 3 per gram
Coagulase Positive *Staphylococcus aureus* - Less than 3 per gram
Bacillus cereus - Not more than 50 per gram
Aerobic Plate Count - Not more than 500 per gram

5.4.2 Liquid concentrate (Class 2). The concentrated liquid infant formula shall be a commercially sterile product. Standard dilution is equal parts of concentrated liquid infant formula and water. When prepared in accordance with label instructions, the infant formula shall supply the labeled nutritional requirements.

5.4.3 Ready-to-use (Class 3). The ready-to-use infant formula shall be a commercially sterile product. Ready-to-use infant formula product is ready-to-use from the primary container. The infant formula shall supply the labeled nutritional requirements.

6. ANALYTICAL REQUIREMENTS. Unless otherwise specified in the solicitation, contract, or purchase order, the analytical requirements for the infant formula products shall comply with this CID, the current Infant Formula Program - Import and Domestic, Chapter 21 - Food Composition, Standards, Labeling and Economics. All testing conducted on infant formula products shall be in compliance with the most current edition of the Official Methods of Analysis of the AOAC International and the FDA, Bacteriological Analytical Manual (BAM) approved methods specific for infant formulas currently in effect.

7. MANUFACTURER'S/DISTRIBUTOR'S PRODUCT ASSURANCE. The manufacturer/ distributor shall certify that the infant formula products provided shall meet the salient characteristics of this CID, conform to their own specifications, standards, and quality assurance practices, and be the same infant formula products offered for sale in the commercial market. The purchaser reserves the right to require proof of conformance.

8. REGULATORY REQUIREMENTS. The delivered infant formula products shall comply with all applicable Federal, State, and local mandatory requirements and regulations relating to the production, transportation, receiving, processing, packaging, labeling, storage, distribution, and sale of infant formula products within the commercial marketplace. The infant formula products shall comply with all applicable provisions of the Federal Food, Drug, and Cosmetic Act, the Infant Formula Act of 1980 and the 1986 Amendments, the Fair Packaging and Labeling Act, and regulations promulgated thereunder.

9. QUALITY ASSURANCE PROVISIONS. All infant formula plants producing infant formula under this CID shall comply with all applicable requirements of the Food and Drug Administration (FDA) Infant Formula Act of 1980 and the 1986 Amendments, and the current edition of the Infant Formula Program - Import and Domestic, Chapter 21 - Food Composition, Standards, Labeling and Economics. The production, transportation, processing, handling, sampling, analysis, labeling, and sale of infant formula products shall also comply with said regulations.

10. PACKAGING. Preservation, packaging, packing, labeling, and case marking shall be commercial unless otherwise specified in the solicitation, contract, or purchase order. Primary containers shall be packed in corrugated fiberboard shipping containers or corrugated fiberboard trays with plastic shrink wrap that will provide infant formula protection against loss and damage during multiple shipment, handling, and storage. Each powder infant formula container shall include a measuring scoop and be equipped with a plastic lid for use after opening. Cans of infant formula shall be free of excessive dents and distortions and free from rust or other evidence of improper storage.

11. REFERENCE NOTES.

11.1 FDA contact. Infant Formula Team, HFS-831, Division of Nutrition Science and Policy, Office of Nutritional Products, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740-3835, telephone (301) 436-1450 or Fax (301) 436-2639.

11.2 Sources of documents.

11.2.1 Source of information for nongovernmental document are as follows:

Copies of the Official Methods of Analysis of the AOAC International may be obtained from: **AOAC International, 481 North Frederick Avenue, Suite 500, Gaithersburg, MD 20877, telephone (301) 924-7077or on the Internet at: http://www.aoac.org**.

Copies of the American Dairy Products Institute Scorched Particle Standards for Dry Milks of may be obtained from: **American Dairy Products Institute, 300 West Washington, Street, Suite 400, Chicago, IL 60606-1704, telephone (312) 782-4888 or Fax (312) 782-5299, or via E-mail: dmeyer@americandairyproducts.org or on the Internet at: http://www.americandairyproducts.com**.

12.2.2 Sources of information for governmental documents are as follows:

Applicable provisions of the Fair Packaging and Labeling Act are contained in 16 CFR Parts 500 to 503. Applicable provisions of the Federal Food, Drug, and Cosmetic Act, including the Infant Formula Act of 1980 and the 1986 Amendments are contained in 21 CFR Parts 1 to 199. These documents may be purchased from: **Superintendent of Documents, New Orders, P.O. Box 371954, Pittsburgh, PA 15250-7954. Credit card (MasterCard or Visa) purchases are made by calling the Superintendent of Documents on (202) 512-1800 or on the Internet at: http://www.access.gpo.gov/nara.**

The FDA Bacteriological Analytical Manual Methods of Analysis (BAM) is available on the Internet at: **http://www.cfsan.fda.gov/~ebam/bam-toc.html.**

Copies of this CID and beneficial comments, recommendations, additions, deletions, clarifications, etc., and any data which may improve this CID are available from and/or provided to: **Head, Food Quality Assurance Staff, Fruit and Vegetable Programs, Agricultural Marketing Service, USDA, STOP 0243, 1400 Independence Avenue, SW, Washington, DC 20250-0243, telephone (202) 720-9939, Fax (202) 690-0102, via E-mail: FQAStaff@usda.gov or on the Internet at: http://www.ams.usda.gov/fv/fvqual.htm.**

MILITARY INTERESTS:

NONE: The Department of Defense has determined that no military activity has an official interest in this Commercial Item Description.

CIVIL AGENCY COORDINATING ACTIVITIES:

DOJ - BOP
HHS - FDA
USDA - FSA
USDA - FNS
USDA - FV

PREPARING ACTIVITY:

USDA - FV